



### REMARKS

Claims 1-24 were pending. Claim 1 has been amended. Claims 5 and 16-23 have been canceled. Claims 1-4, 6-15, and 24 will be pending upon entry of the instant amendment. No new matter has been added. Support for the amendment to claim 1, can be found, for example, at least in claim 5 as originally pending.

Cancellation of and/or amendments to the claims should in no way be construed as an acquiescence to any of the Examiner's objections and/or rejections. The cancellation of the claims is being made solely to expedite prosecution of the above-identified application. Applicant reserves the option to further prosecute the same or similar claims in the present or another patent application.

Applicant submits herewith the remaining references missing from the previously filed Information Disclosure Statement.

#### ***Objection to the Specification under 35 U.S.C. § 112, first paragraph***

The specification is objected to under 35 U.S.C. § 112, first paragraph, as "failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure."

In particular, the Examiner alleged that "Applicant fails to set forth the criteria that defines neither a[n] 'energy kinase modulator' or a[n] 'energy transmitting kinase modulator.'" Furthermore, the Examiner noted that the claims "read on all 'energy kinase modulator(s)' or all 'energy transmitting kinase modulator(s),' necessitating an exhaustive search for the embodiments suitable to practice the claimed invention."

Applicant respectfully submits that the specification does set forth criteria which defines both energy kinase modulators and energy transmitting kinase modulators. For example, Applicant discusses assays which can be used to identify modulators in the instant specification at least at, page 10, line 16 through page 11, line 5, page 13, line 26 through page 14, line 17, page 20, line 3 through page 24, line 29, and in the cited references.

Therefore, Applicant respectfully requests that this objection to the specification under 35 U.S.C. § 112, first paragraph be withdrawn.

#### ***Rejection of Claims 1-4 and 6-24 under 35 U.S.C. § 112, first paragraph***

Claims 1-4 and 6-24 are rejected under 35 U.S.C. § 112, first paragraph, as "failing to adequately teach how to make and/or use the invention." In particular, the Examiner states that claims 1-4 and 6-24 are rendered indefinite by the phrases "energy

kinase modulator” or “energy transmitting kinase modulator,” because “criteria defining [the phrases] are not set forth in the specification.”

Claims 1-4, 6-8, and 24 no longer recite the phrase “energy kinase modulator” and claims 16-23 have been canceled, thus rendering the rejection of these claims under 35 U.S.C. §112, first paragraph, moot.

Applicant respectfully submits that the specification does set forth criteria which define energy transmitting kinase modulators. For example, Applicant discusses assays which can be used to identify modulators in the instant specification at least at, page 10, line 16 through page 11, line 5, page 13, line 26 through page 14, line 17, page 20, line 3 through page 24, line 29, and in the cited references.

Therefore, Applicant respectfully requests that this rejection of claims 9-15 under 35 U.S.C. § 112, first paragraph be withdrawn.

***Rejection of Claims 16-23 under 35 U.S.C. § 112, second paragraph***

Claims 16-23 are rejected under 35 U.S.C. § 112, second paragraph, as “being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.”

Claims 16-23 have been canceled, thus rendering this rejection moot.

***Rejection of Claims 1-14, 16-19, 21-22, and 24 under 35 U.S.C. § 102(b)***

Claims 1-14, 16-19, 21-22 and 24 are rejected under 35 U.S.C. § 102(b) as being anticipated by Maneesub *et al.*, *Neurochem. Int.* (1993) 22(5):487-491 (hereinafter “Maneesub *et al.*”) or Behl *et al.*, *Biochem. Biophys. Res. Comm.* (1992) 186(2):944-50 (hereinafter “Behl *et al.*”).

Applicant claims methods for treating energy related associated states by administering to a subject an effective amount of bepridil, verapamil, nifedipine, nisoldipine, theophylline, semecarpus anacardium nut extract, 2-dioxy-D-glucose, caffeine, dipyridamole, papaverine, or cyclamidomycin. Applicant also claims methods for modulating an energy transmitting kinase in a subject. Claims 16-23 have been canceled, thus rendering their rejection moot.

Maneesub *et al.* discuss partial restoration of choline acetyltransferase activity in aged rat brains after the administration of vitamin E. Maneesub *et al.* do not teach or suggest the modulation of an energy transmitting kinase nor methods of treating disorders by modulating an energy transmitting kinase. In contrast, Maneesub *et al.* discuss methods involving choline acetyltransferase, which is not a kinase. Furthermore, Maneesub *et al.* do not teach or suggest methods of treating energy related associated

states using bepridil, verapamil, nifedipine, nisoldipine, theophylline, semecarpus anacardium nut extract, 2-dioxy-D-glucose, caffeine, dipyridamole, papaverine, or cyclamidomycin.

Behl *et al.* discuss the use of vitamin E for protection of nerve cells from amyloid  $\beta$  protein toxicity. Behl *et al.* do not teach or suggest the modulation of a energy transmitting kinase. Furthermore, Behl *et al.* also fail to teach or suggest methods for treating an energy related associated state using bepridil, verapamil, nifedipine, nisoldipine, theophylline, semecarpus anacardium nut extract, 2-dioxy-D-glucose, caffeine, dipyridamole, papaverine, or cyclamidomycin.

Therefore, Applicant respectfully requests that this rejection of claims 1-14 and 24 under 35 U.S.C. § 102(b) be withdrawn.

***Rejection of Claims 1-24 under 35 U.S.C. § 103(a)***

Claims 1-24 are rejected under 35 U.S.C. § 103(a) as being as being unpatentable over Maneesub *et al.* and Behl *et al.*

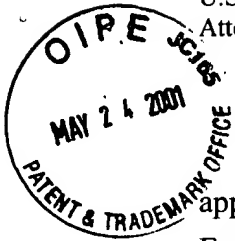
As discussed above, Applicant claims methods for treating energy related associated states by administering to a subject an effective amount of bepridil, verapamil, nifedipine, nisoldipine, theophylline, semecarpus anacardium nut extract, 2-dioxy-D-glucose, caffeine, dipyridamole, papaverine, or cyclamidomycin. Applicant also claims methods for modulating an energy transmitting kinase in a subject. Claims 16-23 have been canceled, thus rendering their rejection moot.

Maneesub *et al.* discuss partial restoration of choline acetyltransferase activity in aged rat brains after the administration of vitamin E.

Behl *et al.* discuss the use of vitamin E for protection of nerve cells from amyloid  $\beta$  protein toxicity.

Neither Maneesub *et al.* nor Behl *et al.* alone or in combination teach or suggest Applicant's claimed invention. Neither Maneesub *et al.* nor Behl *et al.* teach or suggest the modulation of a kinase in a subject. Furthermore neither Maneesub *et al.* nor Behl *et al.* teach or suggest the treatment of an energy associated related state by administering to a subject an effective amount of bepridil, verapamil, nifedipine, nisoldipine, theophylline, semecarpus anacardium nut extract, 2-dioxy-D-glucose, caffeine, dipyridamole, papaverine, or cyclamidomycin.

Therefore, Applicant respectfully requests that this rejection of claims 1-4, 6-15 and 24 under 35 U.S.C. § 103(a) be withdrawn.



**CONCLUSION**

In view of the remarks set forth above, it is respectfully submitted that this application is in condition for allowance. If there are any remaining issues or if the Examiner believes that a telephone conversation with Applicant's Attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at (617) 227-7400.

Date: May 21, 2001

Respectfully Submitted,

LAHIVE & COCKFIELD, LLP  
Attorneys at Law

By

A handwritten signature in black ink, appearing to be "E. Hanley", written over a horizontal line.

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**Version with Markings to Show Changes Made**

1. (Amended) A method of treating an energy related associated state, comprising administering to a subject an effective amount of bepidil, verapamil, nifedipine, nisoldipine, theophylline, semecarpus anacardium nut extract, 2-dioxy-D-glucose, caffeine, dipyridamole, papaverine, or cyclamido~~mycin-an energy kinase modulator~~, such that an energy related associated state is treated.